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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,593	08/26/2003	Fei Huang	D0273 NP	5265

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,593	HUANG ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

20

DETAILED ACTION

Claims 1-40 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a DNA array, classified in class 536, subclass 23.2.

II. Claims 8-14, drawn to a protein array, classified in class 530, subclass 350.

III. Claims 16-19, drawn to a method of identifying a modulator using a DNA array, classified in class 435, subclass 6.

IV. Claims 20-23, drawn to a method of identifying a modulator using a protein array, classified in class 435, subclass 7.1.

V. Claims 24-26, drawn to a plurality of cells, classified in class 435, subclass 325.

VI. Claims 27-29, in part, drawn to a method for identifying predictive polynucleotides using a plurality of cells, classified in class 436, subclass 63.

VII. Claims 27-29, in part, drawn to a method for identifying predictive polypeptides using a plurality of cells, classified in class 436, subclass 86.

VIII. Claims 31-34, drawn to a DNA method for predicting response to treatment using a plurality of cells, classified in class 435, subclass 6.

IX. Claims 35-38, drawn to a protein method for predicting response to treatment using a plurality of cells, classified in class 435, subclass 7.1.

X. Claim 39, in part, drawn to a method for identifying compounds that bind to a tyrosine kinase, classified in class 435, subclass 15.

XI. Claim 39, in part, drawn to a method for identifying compounds that modulate a tyrosine kinase, classified in class 435, subclass 15.

XII. Claim 40, drawn to a method of treatment using a modulator of a tyrosine kinase biomarker polypeptide, classified in class 514, subclass 1.

For each of Inventions I-XII above, restriction to one of the following is also required under 35 USC 121 and 327. Therefore, election is required of one of Inventions I-XII and one of Inventions (A)-(ZZZ...).

For Inventions I, III, VIII elect one of:

(A)-(Z...) A specific complement of polynucleotides provided in Tables 2-5

For Inventions II, IV, IX-XII, elect one of:

(AA)-(ZZ...) A specific complement of polypeptides provided in Tables 2-5

For Inventions V-VII, elect one of:

(AAA)-(ZZZ...) A specific complement of cells provided in Table 1

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The DNA array of Invention I is related to the protein array of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

Invention V is unrelated to Inventions I and II because the product of Invention V is a physically and functionally distinct chemical entity from the products of Inventions I and II.

Inventions III, IV, and VI-XII are independent because the methods of Inventions III, IV, and VI-XII comprise different steps, utilize different products and/or produce different results.

The methods of Invention III are related to the DNA array of Invention I as a product and process of using. The inventions are distinct because the DNA array can also be used for making the encoded proteins.

Invention I is unrelated to Inventions IV and VI-XII because the methods of Inventions IV and VI-XII can neither use the DNA array of Invention I nor be used to make said DNA array.

The methods of Inventions IV, X, and XI are related to the protein array of Invention II as a product and process of using. The inventions are distinct because the protein array can also be used for screening antibodies.

Invention I is unrelated to Inventions VI-IX and XII because the methods of Inventions VI-IX and XII can neither use the protein array of Invention I nor be used to make said protein array.

The methods of Inventions VI-IX are related to the cells of Invention V as a product and process of using. The inventions are distinct because the cells can also be used for isolating expressed proteins.

Invention V is unrelated to Inventions III, IV, and XII because the methods of Inventions III, IV, and XII can neither use the cells of Invention V nor be used to make said cells.

A search for more than on of Inventions I-XII would be a burden on the Office for the following reasons.

The search of Invention I would not encompass a search for Invention II, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Invention II, class 530, subclass 350, would not encompass a search for Invention I, which would also include searching class 435, subclasses 69.1, 252.3, and 320.1 as well as class 536, subclass 23.2. Thus, a search of either Invention I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Because the product of Invention V is a structurally and/or functionally distinct entity from the products of Inventions I and II are, a search for Invention V would not encompass a search for Invention I or II, or vice versus, and searching Invention V with Invention I or II would be a burden on the Office.

Because the methods of Inventions III, IV, and VI-XII comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not

encompass a search for any other invention and searching all of Inventions III, IV, and VI-XII, or a subset thereof, would be a burden on the Office.

A search for the products of Inventions I, III, or V would not encompass a search for the methods of Inventions III, IV, and VI-XII, or vice versa, because said methods are not the only methods of making and/or using said products. Thus, a search of any of Inventions I, III, or V with any of Inventions III, IV, and VI-XII would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Claim 15 links Inventions III and IV. Claim 30 links Inventions VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the

linking claims, Claims 15 and 30. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.